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109TH CONGRESS
2D SESSION

H. R. 5887

To improve vaccine safety research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2006

Mr. WELDON of Florida (for himself and Mrs. MALONEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To improve vaccine safety research, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Vaccine Safety and Public Confidence Assurance Act of 2006'' .

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The Nation's vaccine program has greatly reduced human suffering from infectious disease by preventing and reducing the outbreak of vaccine-preventable diseases.

(2) The prestigious scientific journal Nature has noted that to maintain public confidence in vaccines ''there is a strong case for a well-resourced independent agency that commends the trust of both the government and the public''. Nature 439, 1–2.

(3) Public confidence in governmental vaccine-safety monitoring agencies is critical to building and maintaining public confidence in vaccine safety.

(4) Actual or perceived conflicts of interest undermine the credibility of vaccine-safety assurances and reports issued by those with conflicts of interest.

(5) The Federal Government has a responsibility to take all steps feasible to ensure that research evaluating the safety of existing and future vaccines is of the highest quality and free from conflicts of interest.

(6) The Centers for Disease Control and Prevention is responsible for promoting both high immunization rates and vaccine safety, duties perceived by some to constitute a conflict of interest.

(7) The actual or perceived conflict of interest between vaccine promotion and vaccine safety has been compounded by the fact that vaccine-safety programs and the National Immunization Program have needed to compete against each other for funds. Funding for vaccine-safety research should be completely independent from other vaccine-related budget priorities.

(8) There are numerous vaccines presently in the development pipeline for disease prevention and treatment, and it is critical that the Nation develop longer term and more specific safety monitoring mechanisms.

(9) It is critical that the Federal Government revamp vaccine-safety monitoring programs to focus increasingly on developing prevaccination screening tools to prevent injury, thereby raising public confidence and reducing vaccine injuries.

(10) The current structure for monitoring for vaccine safety, postlicensure, primarily focuses on epidemiology. There is inadequate funding directed toward independent research, including research directed at understanding underlying biological mechanisms and biological susceptibilities and designed to

understand why some children and adults develop serious adverse outcomes after vaccination.

(11) Because most serious adverse reactions to vaccines are rare, epidemiology studies may be limited in their ability to establish or rule out causal association or biological plausibility.

(12) The vaccine-safety monitoring functions of the Department of Health and Human Services have tended to focus on monitoring for acute adverse events rather than chronic adverse events. There is little coordination and inadequate effort to investigate the biological mechanisms underlying vaccine-related adverse events.

SEC. 3. PURPOSE.

The purpose of this title is to direct that vaccine safety monitoring and research focus on active surveillance, researching biological mechanisms for acute and chronic adverse events following vaccination, developing prevaccination screening methods within a framework that is free from actual and perceived biases, and developing a vaccine safety research agenda.

SEC. 4. ESTABLISHMENT OF AGENCY FOR VACCINE SAFETY EVALUATION.

Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended by adding at the end the following:

"Subtitle 3—Agency for Vaccine Safety Evaluation

"SEC. 2141. ESTABLISHMENT.

''There is established in the Office of the Secretary the Agency for Vaccine Safety Evaluation, to be headed by the Director for Vaccine Safety Evaluation.

"SEC. 2142. AUTHORITIES.

''(a) IN GENERAL.—With respect to vaccines, the Director for Vaccine Safety Evaluation—

''(1) shall conduct or support safety research, including research on—

''(A) acute and chronic adverse reactions, including with respect to subpopulations;

''(B) components of vaccines, including additives, adjuvants, and preservatives;

''(C) delivery mechanisms; and

''(D) the potential presence of adventitious agents in vaccines; and

''(2) shall conduct or support long- and short-term monitoring of vaccines for which a biologics li-

cense is in effect under section 351 of the Public Health Service Act;

''(3) shall develop a vaccine safety research agenda;

''(4) shall conduct or support research across a range of disciplines, including molecular genetics, toxicology, pharmacokinetics, cell biology, neurology, immunology, pharmacogenomics, virology, and epidemiology;

''(5) shall conduct or support research to address issues raised in claims of injury brought before the Secretary, the Attorney General of the United States, and State and Federal courts;

''(6) shall develop, evaluate, and test hypotheses, when appropriate, about potential adverse reactions, including those generated by the Department of Defense, the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, other governmental agencies, and external researchers;

''(7) shall, on a regular basis, evaluate, report on, and explore means to promote the compliance of health care providers and vaccine manufacturers with Federal requirements for reporting adverse re-

actions related to licensed vaccines, including the requirements of section 2125(b);

''(8) shall conduct or support research to evaluate reports of injury following vaccine administration for the purpose of developing tests to prescreen individuals and subpopulations at greater risk of injury;

''(9) shall conduct or support research to evaluate biological mechanisms of injury for the purpose of eliminating or reducing the risk of such injury through better prescreening tools or through modification of vaccines;

''(10) shall conduct long-term monitoring of new or altered vaccines, including by monitoring the effects of changes to the recommended childhood and adolescent immunization schedule of the Centers for Disease Control and Prevention; and

''(11) shall provide, in conjunction with the National Library of Medicine, a clearinghouse for prelicensure and postlicensure studies of vaccines and make such clearinghouse publicly accessible by means of the Internet.

''(b) PERSONNEL.—In carrying out this subtitle, the Director for Vaccine Safety Evaluation—

''(1) may not employ any individual as an officer or employee in a position in level I, II, III, IV,

or V of the Executive Schedule or level GS–15 of the General Schedule if the individual has been employed within the preceding 5 years—

''(A) by the Centers for Disease Control and Prevention or the Food and Drug Administration to carry out any function relating to monitoring, or research on, adverse reactions related to a licensed vaccine or any function related to vaccine development;

''(B) by the National Institutes of Health to carry out any function relating to vaccine development; or

''(C) by a vaccine manufacturer; and

''(2) shall ensure that all personnel assigned to carry out functions relating to vaccine monitoring or research on adverse reactions related to vaccines do not have any related professional, familial, or financial conflict of interest.

''(c) GRANT APPLICANTS.—In awarding any grant relating to research on adverse reactions to vaccines, the Director for Vaccine Safety Evaluation—

''(1) shall require applicants to disclose (and update every 6 months) all potential conflicts of interest;

''(2) shall provide all disclosures under paragraph (1) to the advisory council for consideration as part of the council's review of the application for the grant; and

''(3) shall ensure that the applicant for the grant does not have—

''(A) any financial conflict of interest that might compromise the research findings, such as holding a related patent or having a family member who holds a related patent; or

''(B) any conflict of interest resulting from the applicant's association with an entity with direct or indirect financial interest in the outcomes of vaccine-safety research, such as receiving money or an in-kind contribution from a manufacturer of the particular vaccine or vaccine components to be investigated pursuant to the grant.

''(d) VACCINE SAFETY DATALINK PROJECT.—

''(1) IN GENERAL.—The Director for Vaccine Safety Evaluation shall have the responsibility for maintaining access to and overseeing the Vaccine Safety Datalink Project (and any successor vaccine database).

''(2) RELATION TO CDC AND FDA.—The Director for Vaccine Safety Evaluation—

''(A) shall ensure that the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs have access to the Vaccine Safety Datalink Project to the full extent necessary to conduct or support monitoring, or research on, acute adverse reactions related to any licensed vaccine; and

''(B) shall consider any comments or recommendations of the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs regarding the Vaccine Safety Datalink Project.

''(3) RESPONSIBILITIES.—In carrying out this subsection, the Director for Vaccine Safety Evaluation—

''(A) shall facilitate external access to the Vaccine Safety Datalink Project for purposes of research, including by—

''(i) requiring each participating health care provider or health maintenance organization to use a facilitator and sufficient staff for the purpose of assisting external researchers in navigating the data

collection systems of the provider or organization;

''(ii) at the discretion of the Director, reimbursing the provider or organization for the salaries of such facilitator and staff and any other expenses incurred for such purpose;

''(iii) allowing researchers to access data that is collected through the Vaccine Safety Datalink Project, or published after derivation from data that is so collected, for review and duplication;

''(iv) requiring a researcher seeking such access to demonstrate, for the proposed research, the approval of not more than one institutional review board—

''(I) from not more than one participating health care provider or health maintenance organization; or

''(II) established by the Secretary or an agency of the Department of Health and Human Services; and

''(v) developing guidelines for data sharing, including guidelines for making publicly accessible—

''(I) a clarification of the types of studies possible with the Vaccine Safety Datalink Project;

''(II) a categorization of the types of studies possible with the Vaccine Safety Datalink Project; and

''(III) a delineation of the skills necessary to work with the Vaccine Safety Datalink Project; and

''(B) in carrying out subparagraph (A), may deny access to the Vaccine Safety Datalink Project for purposes of research that is not conducted or supported by the Agency only if the Director for Vaccine Safety Evaluation determines that—

''(i) the research is not technically feasible because—

''(I) the requested data are not available in the database;

''(II) enough individuals are not represented in the database with the exposures and outcomes of interest to study the proposed hypothesis; or

''(III) the proposed statistical tests are not possible with the available data; or

''(ii) the researchers fail to demonstrate core competencies in the basic skills needed to analyze the relevant data;

''(C) shall provide for transparency, including by—

''(i) making publicly available the results of studies conducted through the Vaccine Safety Datalink Project; and

''(ii) maintaining archives of data sets in the Vaccine Safety Datalink Project for not less than 7 years;

''(D) shall ensure that, when external researchers access data that is collected through the Vaccine Safety Datalink Project, individually identifiable information is removed to the extent necessary to preserve patient confidentiality; and

''(E) may take such other actions and impose such requirements as the Director for Vaccine Safety Evaluation deems necessary to facilitate external or public access to the database without compromising patient confidentiality.

''(e) REVIEW OF INTERNATIONAL ACTIVITIES.—Not later than 18 months after the date of the enactment of this subtitle, the Director for Vaccine Safety Evaluation shall—

''(1) complete a thorough review of all functions transferred to the Agency under section 2144 relating to international agreements, partnerships, and activities in which the United States Government has a fiduciary role, identify any related conflicts of interest, and develop and implement a plan to reduce such conflicts to the extent possible; and

''(2) submit a report to the Congress containing the results of the review conducted under paragraph (1), describing the conflicts of interests identified under such paragraph, and including the plan developed under such paragraph.

''(f) FELLOWSHIP PROGRAM.—

''(1) ESTABLISHMENT.—The Director for Vaccine Safety Evaluation may establish a program of awarding fellowships to individuals for research on vaccine safety.

''(2) REQUIREMENTS.—The Director for Vaccine Safety Evaluation may not award a fellowship to an individual for research under this subsection unless the individual agrees—

''(A) to refrain from accepting any payment or other benefit for such research from a manufacturer of a vaccine or vaccine component to be subject to the research;

''(B) to refrain from employment by, or acceptance of payment from, a vaccine manufacturer or any organization that receives substantial funding from a vaccine manufacturer before the date that is 2 years after the end of such research; and

''(C) to disclose (and update every 6 months) all potential conflicts of interest.

''(3) APPLICATION.—To seek a fellowship under this subsection, an individual shall submit to the Director for Vaccine Safety Evaluation an application in such form, in such manner, and containing such information as the Director for Vaccine Safety Evaluation may reasonably require.

''(4) PEER REVIEW.—The Director for Vaccine Safety Evaluation shall establish peer review mechanisms to evaluate applications for fellowships under this subsection.

''(g) PEER REVIEW.—

''(1) IN GENERAL.—The requirements of section 492 (relating to peer review) shall apply to re-

search and development conducted or supported by the Agency in the same manner and the to same extent as such requirements apply to research and development conducted or supported by the National Institutes of Health.

''(2) TECHNICAL AND SCIENTIFIC PEER REVIEW GROUPS.—The Director for Vaccine Safety Evaluation may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups as are needed to carry out the requirements of this subtitle and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

''(h) FDA INFORMATION.—At the request of the Director for Vaccine Safety Evaluation, the Commissioner of Food and Drugs shall provide the Director with complete access to all vaccine-related information submitted to the Food and Drug Administration by vaccine manufacturers, irrespective of whether the information was sub-

mitted before or after approval of the vaccine under section 351. The Director shall keep such information confidential to the same extent as the Commissioner of Food and Drugs is required to keep such information confidential, and the Director shall not disclose such information under section 552 of title 5, United States Code .

''(i) REPORT.—

''(1) SUBMISSION.—Not less than twice each year, the Director for Vaccine Safety Evaluation shall submit a report on the Agency's activities under this section to the Advisory Committee on Immunization Practices, the National Vaccine Advisory Committee, the National Vaccine Program Office, the National Vaccine Injury Compensation Program, the Health Resources and Services Administration, and any other entity deemed appropriate by the Director or by the Secretary of Health and Human Services.

''(2) PUBLIC AVAILABILITY.—The Director for Vaccine Safety Evaluation shall make each report under this subsection publicly available.

''SEC. 2143. POSTMARKETING VACCINE SAFETY.

''(a) SURVEILLANCE AND CLINICAL TRIALS.—

''(1) IN GENERAL.—The Director for Vaccine Safety Evaluation, in consultation with the Commis-

sioner of Food and Drugs, shall require the manufacturer of each covered vaccine to provide for post-marketing surveillance and clinical testing for any acute or chronic adverse reactions associated with the vaccine.

''(2) REQUIREMENTS.—The Director for Vaccine Safety Evaluation shall require the following:

''(A) Postmarketing surveillance and clinical testing under paragraph (1) shall be conducted—

''(i) by one or more individuals referred to the advisory council by the manufacturer or by the Agency, recommended by the advisory council under section 2145(b)(3), and approved by the Director for Vaccine Safety Evaluation under paragraph (3); and

''(ii) in accordance with a research protocol referred to the advisory council by the manufacturer or by the Agency, recommended by the advisory council under section 2145(b)(3), and approved by the Director for Vaccine Safety Evaluation.

''(B) The data and analysis of post-marketing surveillance and clinical testing

under paragraph (1) shall be made available for objective, independent evaluation.

''(3) APPROVAL OF RESEARCHERS.—The Director for Vaccine Safety Evaluation may not approve an individual for the purpose of conducting postmarketing surveillance or clinical testing under paragraph (1) unless the individual demonstrates to the Director's satisfaction that the individual has no present conflict of interest that might compromise such surveillance or testing, including any employment or financial relationship with a vaccine manufacturer.

''(4) DEFINITION.—For purposes of this subsection, the term 'covered vaccine' means a vaccine licensed under section 351 after January 1, 2006.

''(b) RELATION TO CDC, FDA, AND VAERS.—This subtitle shall not be construed to diminish the authority of the Director of the Centers for Disease Control and Prevention or the Commissioner of Food and Drugs to implement the Vaccine Adverse Event Reporting System. The postmarketing surveillance conducted by the Director for Vaccine Safety Evaluation under this section shall be in addition to the postmarkeing surveillance conducted under the Vaccine Adverse Event Reporting System.

''(c) RECOMMENDATIONS ON VACCINE SAFETY.—

''(1) GRANTS.—If more than 1 vaccine is licensed under section 351 for the purpose of preventing or mitigating the effects of the same disease, the Director for Vaccine Safety Evaluation may award grants to conduct comparative studies to determine, for each such vaccine, whether the vaccine is associated with fewer acute or chronic serious adverse reactions (in the population as a whole or in any subpopulation) than any other vaccine licensed for the purpose of preventing or mitigating the effects of the same disease. Such studies may focus on administering vaccines in isolation or in combination with other vaccines.

''(2) DETERMINATION.—If the Director for Vaccine Safety Evaluation determines that a vaccine described in paragraph (1) is associated with fewer acute or chronic adverse reactions (in the population as a whole or in any subpopulation) than another vaccine licensed for the purpose of preventing or mitigating the effects of the same disease, the Director shall make this determination publicly available.

''(d) REGISTRATION OF CLINICAL TRIALS.—

''(1) REQUIREMENT.—The Director for Vaccine Safety Evaluation shall require the manufacturer of a vaccine that is licensed under section 351, or for

which the manufacturer will seek licensure under section 351, to register in a qualified public registry each clinical trial conducted or supported by the manufacturer with respect to the vaccine, irrespective of whether such trial is suspended before completion.

''(2) MINIMUM INFORMATION.—In carrying out subsection (a), the Director for Vaccine Safety Evaluation shall require the manufacturer to include in the registration for each clinical trial the following information:

''(A) A unique identifying number.

''(B) A statement of each intervention and comparison studied.

''(C) A statement of the study hypothesis.

''(D) Definitions of the primary and secondary outcome measures.

''(E) Eligibility criteria.

''(F) Key trial dates (including the registration date, the anticipated or actual start date, the anticipated or actual date of last follow-up, the planned or actual date of closure to data entry, and the date on which trial data is considered to be complete).

''(G) The target number of subjects.

''(H) The funding source.

''(I) Contact information for the principal investigator.

''(J) Such other information as the Director may require.

''(3) TIMING OF REGISTRATION.—In carrying out subsection (a), the Director for Vaccine Safety Evaluation shall require the manufacturer to register each clinical trial—

''(A) if the trial starts on or after the date of the enactment of this section, not later than the onset of patient enrollment; and

''(B) if the trial starts before the date of the enactment of this section, not later than the end of the 90-day period following such date of enactment.

''(4) DEFINITIONS.—In this subsection:

''(A) The term 'clinical trial' means a research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

''(B) The term 'qualified public registry' means a registry that—

''(i) is accessible to the public at no charge;

''(ii) is open to all prospective registrants;

''(iii) is managed by a nonprofit organization or a Federal, State, or local governmental entity;

''(iv) has in effect a mechanism to ensure the validity of the registration data;

''(v) is electronically searchable; and

''(vi) includes, for each clinical trial, each category of information described in paragraph (2).

''(5) APPLICATION.—This subsection applies only with respect to clinical trials that are ongoing on, or start on or after, July 1, 2006.

''SEC. 2144. TRANSFER OF CDC FUNCTIONS RELATING TO MONITORING ADVERSE REACTIONS RELATED TO LICENSED VACCINES.

''(a) TRANSFER OF CDC FUNCTIONS.—Effective on the date that is 1 year after the date of the enactment of this subtitle, there are transferred to the Agency all the functions, assets, and obligations of the Centers for Disease Control and Prevention relating to—

''(1) the Vaccine Safety Datalink Project;

''(2) the Clinical Immunization Safety Assessment Centers; or

''(3) any other post-licensure vaccine safety monitoring activities.

''(b) ORDERLY TRANSFER.—The Secretary of Health and Human Services shall take such steps as are necessary to ensure the orderly transfer under this section of functions, assets, and obligations from the Centers for Disease Control and Prevention.

''(c) RULE OF CONSTRUCTION.—Except with respect to the activities specified in subsection (a), nothing in this subtitle shall be construed to transfer or limit the authority of the Director of the Centers for Disease Control and Prevention to conduct surveillance and response activities with respect to vaccine safety or effectiveness, including with respect to acute adverse reactions.

''SEC. 2145. ADVISORY COUNCIL.

''(a) ESTABLISHMENT.—The Secretary shall establish in the Agency an advisory council.

''(b) DUTIES.—The advisory council shall—

''(1) formulate recommendations on the need for new or improved research on licensed vaccines;

''(2) develop and annually update a vaccine safety research agenda;

''(3) recommend individuals and research protocols for purposes of section 2143(a)(2)(A);

''(4) if potentially vaccine-related toxicological damage or subacute infection is observed in vitro, in laboratory animals, or in clinical testing, formulate recommendations on conducting laboratory and clinical research even in the absence of epidemiological evidence;

''(5) not later than 2 weeks after each quarterly meeting of the advisory council, submit to the Agency a report that includes a summary of the presentations made at the meeting, a list of hypotheses proposed, and the recommendations of the advisory council on research described in paragraph (1);

''(6) review each application submitted to the Director for Vaccine Safety Evaluation for a grant or other assistance related to vaccine research;

''(7) make recommendations to the Director for Vaccine Safety Evaluation regarding each such application;

''(8) make recommendations to the Secretary of Health and Human Services regarding vaccine safety;

''(9) not less than quarterly, submit a report to the Secretary of Health and Human Services regarding vaccine safety efforts; and

''(10) make publicly available—

''(A) each report submitted under paragraph (9); and

''(B) a transcript of each meeting of the advisory council.

''(c) EFFECT OF RECOMMENDATIONS.—The Director for Vaccine Safety Evaluation may not approve any application for a grant or other assistance related to vaccine research until the Director has considered the recommendations of the advisory council regarding such research. If the Director decides to approve or disapprove any such application contrary to the recommendations of the advisory council, the Director shall provide the advisory council with, and make publicly available, a detailed, written explanation of the reasons for the decision.

''(d) MEMBERSHIP.—

''(1) COMPOSITION.—The advisory council shall be composed of 18 members appointed by the Secretary, including the following:

''(A) Not more than 2 representatives of the vaccine manufacturing industry.

''(B) One practicing pediatrician.

''(C) One infectious disease expert.

''(D) Five adults who are each—

''(i) a victim of a vaccine injury; or

''(ii) a parent of the victim of a vaccine-related injury.

''(E) One representative of the general public who—

''(i) is not the victim of a vaccine injury; and

''(ii) does not have a conflict of interest described in paragraph (1)(A), (1)(B), or (2) of section 2142(b).

''(F) One toxicologist.

''(G) One neurologist.

''(H) One geneticist.

''(I) One immunologist.

''(J) One State or local public health officer.

''(K) Not less than 4 and not more than 6 additional representatives.

''(2) QUALIFICATIONS.—In appointing the members of the Commission, the Secretary shall ensure that not less than one-third of the members of the advisory council are selected from among individuals who have a vaccine-related injury or who

have an immediate family member with a vaccine-related injury (irrespective of whether there is a judicial or administration finding of such injury).

''(3) CONFLICTS OF INTEREST.—In appointing the members of the Commission, the Secretary shall ensure that such members do not have any related financial conflict of interest. For purposes of this paragraph, the Secretary shall not treat as a conflict of interest the following:

''(A) In the case of a member appointed under paragraph (1)(A) who is employed in the vaccine manufacturing industry, the receipt of a salary or other benefits for such employment.

''(B) In the case of 2 of the members appointed under paragraph (1)(D), any pending claim for compensation for a vaccine-related injury.

''SEC. 2146. FULL-TIME LIAISON.

''The Director for Vaccine Safety Evaluation shall designate an employee of the Agency to serve as a full-time liaison between the Agency and the Department of Defense, the National Institutes of Health, the Food and Drug Administration, and the Centers for Disease Control and Prevention, and any other agency as the Director determines necessary.

"SEC. 2147. DEFINITIONS.

"In this subtitle:

"(1) The term 'advisory council' means the advisory council established pursuant to section 2145.

"(2) The term 'Agency' means the Agency for Vaccine Safety Evaluation.

"(3) The term 'assets' includes contracts, facilities, property, records, unobligated or unexpended balances of appropriations, and other funds or resources (other than personnel).

"(4) The term 'functions' includes authorities, powers, rights, privileges, immunities, programs, projects, activities, duties, and responsibilities.

"(5) The term 'licensed vaccine' means a vaccine with a biologics license in effect under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(6) The term 'personnel' means officers and employees.

"(7) The term 'Project' means the Vaccine Safety Datalink Project.

"SEC. 2148. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated—

"(1) for conducting and supporting research under this subtitle, $80,000,000 for fiscal year 2007; and

''(2) for carrying out responsibilities under this subtitle other than the conduct or support of research, such sums as may be necessary for fiscal year 2007.''.

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